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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/765,564      | 01/27/2004  | William Dubrul       | GTEC 1001-5         | 8126             |

22470 7590 10/09/2007  
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| EXAMINER |
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HOUSTON, ELIZABETH

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| ART UNIT | PAPER NUMBER |
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3731

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10/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/765,564

Applicant(s)

DUBRUL ET AL.

Examiner

Elizabeth Houston

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6,7,10-16,19,20,22-25,27,28 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6,7,10-16,19,20,22-25,27,28 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/27/04 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted claims 29-50 and 52-56 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to an embodiment with a blocking element designed with a braid arrangement whereas the original claims were directed to a blocking element designed with a malecot style.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-50 and 52-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show an example of an alternate embodiment of the blood flow blocking element designed with a braid arrangement. The specification (Para [0053]) states that this is shown in Figs. 9 and 10. However, it is unclear how the embodiment in Figs. 9 and 10 is any different from the embodiment in Fig. 4, which is described in the specification as the malecot style blood flow blocking element. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required

Art Unit: 3731

in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The disclosure is objected to because of the following informalities: Para 0036, line 13 states "the braided device 18", however earlier in the paragraph reference is made several times to "malecot type blocking device 18" and "braided removal device 24".

Appropriate correction is required.

***Claim Objections***

4. Claim 19 objected to because of the following informalities: The amended second line of claim 19, "an elongate member a distal end", is grammatically incorrect. Appropriate correction is required.

***Double Patenting***

5. **Claims 6, 7, 10-13, 15, 16, 19, 20, 22, 23, 25, 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 15 and 16 of U.S. Patent No. 6,669,260 in view of Solano et al. (US 4,921,478).** The patent claims all the features of the instant application except for the "outer distally facing generally funnel surface". The claims of the patent are completely silent to this feature. Solano discloses a similar device which has an outer distally facing generally funnel surface. Since the patent and Solano substantially discloses the same invention it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an outer distally facing generally funnel surface in order to prevent blood or emboli from flowing past the catheter.

6. **Claims 6, 7, 10-16, 19, 20, 22-25 and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,238,412 in view of Solano et al. (US 4,921,478).** The patent claims all the features of the instant application except for the "outer distally facing generally funnel surface". The claims of the patent are completely silent to this feature. Solano discloses a similar device which has an outer distally facing generally

Art Unit: 3731

funnel surface. Since the patent and Solano substantially discloses the same invention it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an outer distally facing generally funnel surface in order to prevent blood or emboli from flowing past the catheter.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 6, 7, 10-16, 19, 20, 22-25, 27, 28 and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Solano et al. (US 4,921,478).**

9. Solano discloses the invention substantially as claimed including an occluder and a method of deploying an occluder that comprises: a catheter having a distal end (Fig. 2), having a blood flow blocking element comprising structural members (28) defining openings there between (27) and positioned near the distal end of the catheter, said blood flow blocking element having a radially compressed insertion state and a radially expanded blocking state (figs. 6a, 6d, 10a, 10b), an actuator (22) associated with said catheter to move said blood flow blocking element from said compressed state to said expanded state (Col 5, lines 54-68)), and said blood flow blocking element in said radially expanded blocking state having an outer distally facing, generally funnel surface

Art Unit: 3731

extending out from said distal end of said catheter (figs. 6d, 8, 10b). The blocking element blocks passage of material around the outside of the catheter and is a malecot style device. An annular membrane (76) that contacts the structural members is an elastomeric impermeable membrane (Col 6, lines 45-56). The actuator (22) extends through the lumen of the catheter (24) distal of said blood flow blocking element and when moved in a proximal direction, engages said blood flow blocking element to switch said blood flow blocking element from said retracted insertion state into said radially expanded blocking state (Col 5, lines 62).

### ***Response to Arguments***

10. Applicant's arguments, see Remarks, filed 07/18/07, with respect to the rejection(s) of claim(s) 1-7, 8-23 under 102(e) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found art under 102(b) as being anticipated by Solano as stated above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

9/29/07

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

9/30/07